Congress of the United States
Washington, DC 20515

May 25, 2018

The Honorable Mick Mulvaney
Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

RE: Advance Notice of Proposed Rulemaking on Regulations of Premium Cigars [Docket No. FDA-2017-N-6107]

Dear Director Mulvaney:

We are writing to you regarding the U.S. Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking (ANPRM) notice published on March 26 regarding the regulation of premium cigars under the Federal Food, Drug, and Cosmetic Act.

Given that the FDA included an unusually extensive list of tiered and complex questions in its ANPRM, we urge the OMB to extend the current 90-day comment period by an additional 90 days – advancing the deadline to September 23, 2018 – which would provide industry and concerned citizens ample time to respond. In addition to working to respond to the ANPRM, the hand-rolled premium cigar industry is simultaneously spending considerable resources preparing to meet the requirements of the August warning label deadline. Therefore, the labeling deadline needs to be paired with the public comment extension date.

As members of the U.S. Congress representing all sectors of the hand-rolled premium cigar industry, we remain concerned that the FDA's regulatory overreach on this issue, which is contrary to Congress' intent under the Family Smoking Prevention and Tobacco Control Act (FSPTCA), will continue to impose greater economic burdens on the manufacturers and retailers of premium cigars.

The ANPRM on Regulations of Premium Cigars contains 24 separate questions, including 18 individual subparts. Specifically, the Cigar Association of America, Inc. noted in its ANPRM comments (enclosed) that the FDA "seeks an all-encompassing, comprehensive response that seeks data, research results, and other information relating to premium cigars, in three separate categories." The current 90-day public comment period is insufficient to garner the kind of "all-encompassing, comprehensive response[s]" that the FDA is seeking. In comparison, the CAA noted that the FDA provided a 120-day public comment period on the "use of menthol in cigarettes (Docket No. FDA-2013-N-0521, and 165 days to respond to its Proposed Rule on N-nitrosonornicotine ("NNN") levels in finished smokeless tobacco products (Docket No. FDA-2016-N-2527)."

Again, we urge the OMB to reexamine the FDA's ANPRM and extend the public comment period and warning label deadline by an additional 90 days. Thank you for your service, and consideration of our request. We look forward to your response.

Sincerely,

Bill Posey
Member of Congress

Tom Cole
Member of Congress

Jim Sensenbrenner
Member of Congress

Don Young
Member of Congress

Chris Collins
Member of Congress

Doug Collins
Member of Congress

Gus Bilirakis
Member of Congress

Charlie Crist
Member of Congress

Ken Calvert
Member of Congress

John Katko
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Brad Wenstrup, MD
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Steve Pearce
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Mike Bost
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